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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,488	07/31/2006	Daniel E Katzman	NEU-102.1P US	9463

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EXAMINER

PATTON, AMANDA K

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,488

Applicant(s)

KATZMAN ET AL.

Examiner

Amanda Patton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/25/06, 3/23/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: page 13, line 23 refers to an international application but does not contain the international application number. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "and combinations thereof" is vague as it is unclear what combinations are being discussed. The examiner has interpreted the claim as containing all three – physical, occupational, and speech therapy - and thus there is a combination thereof since all three are provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 7-8, 14-23, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Bacon et al. (US Pat. 6,492,396).

Regarding **claims 1, 2, 4, 7-8, 20-23, and 25**, Bacon teaches the treatment of multiple sclerosis, Parkinson's disease, and Alzheimer's disease as well as stroke using an effective amount of modafinil in combination with various agents including apomorphine and amphetamine (e.g. Col. 1, line 30- Col. 2, line 30; Col. 4, lines 30-40). It is well known in the art that multiple sclerosis affects cognitive and/or motor function.

Regarding **claims 14-19**, Bacon additionally teaches the administration of a modafinil analog in preferred daily doses including 50, 100, and 200 mg/day. These doses fall within the range of 50 to 600 mg/day, and include a daily dose of 200 mg/day.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon in view of Allen (US Pat. 5,957,873).

Regarding **claim 3**, Bacon discloses the claimed invention except for a neurorehabilitation program that provides physical, occupational, and speech therapy. Allen discloses that it is known in the art to use physical, occupational, and speech therapy for treatment of those suffering from neurological disorders. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating a patient with a neurological disorder as taught by Bacon with the traditional treatments of physical, occupational, and speech therapy as taught by Allen, since such a modification would provide the predictable results of improved treatment of impaired neurological function.

Regarding **claim 5**, Bacon and Allen disclose the claimed invention except for the a physical/sensory protocol comprising a neurostimulus selected from the group consisting of an exercise or task for motor function, an exercise or task for cognitive function, an exercise or task for a combination of motor and cognitive function, a light stimulation, an audio stimulation, a visual stimulation, a tactile stimulation, and combinations thereof. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bacon and Allen with an exercise or task for motor function since it is known in the art that an exercise or task for motor function is used in physical therapy to provided the predictable result of improved treatment of impaired neurological function.

Claims 1, 4, 6, and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rise et al. (US Pat. 6,227,203) in view of Bacon.

Regarding **claims 1, 4, and 6**, Rise discloses the claimed invention including the administration of deep brain stimulation in combination with drug therapy in order to treat an impaired neurological function of an individual who has sustained a brain injury such as those related with Parkinson's disease, (e.g. Abstract) but does not teach the administration of an effective amount of modafinil as the specific drug used in the drug therapy. Bacon teaches the administration of an effective amount of modafinil for treatment of an impaired neurological function. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating an impaired neurological function of an individual who has sustained a brain injury with the inclusion of the drug modafinil as taught in Bacon since such a modification would provide the predictable results of improved treatment of impaired neurological function.

Regarding **claims 9 and 10**, Rise additionally discloses that stimulation might be applied periodically during the period of drug infusion or in response to a patient generated demand (e.g. Figure 24; Col. 16, lines 5-20). This patient generated demand could be an exercise or task to promote or restore an impaired neurological function, and thus the drug modafinil would be administered to an individual prior to or concurrently with the individual performing an exercise or task and stopped after the individual performs an exercise or task and wherein the administration is not resumed until further exercise or task is performed.

Regarding **claims 11-12**, neither Rise nor Bacon expressly teach a period or rest from the administration of modafinil and, after the period of rest, resuming the therapy with a different does and/or a different neurorehabilitation program that those employed initially. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Rise and Bacon in a period or rest and resuming therapy with a different neurorehabilitation program since it was known in the art that adjustment of any therapy program is commonplace and is used to provide the predictable results of improved treatment of impaired neurological function.

Regarding **claim 13**, Rise and Bacon disclose the claimed invention but do not expressly disclose a resting period of 4 to 12 weeks. It would have been an obvious matter of choice to a person of ordinary skill in the art to modify the method of treating a neurological disorder with a resting period of 4 to 12 weeks, because Applicant has not disclosed that a resting period of 4 to 12 weeks provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any period of rest as taught by Rise and Bacon, because it provides a period of recovery and since it is an arbitrary choice of a rest period length.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon. Bacon discloses the claimed invention except for a traumatic brain injury that is the result of a fall on a hard surface, a vehicular accident, or a strike on the head. Bacon does disclose, however, providing treatment for cerebral ischemia, which can be caused as the result of a fall on a hard surface, a vehicular accident, or a strike on the head. It would have been obvious to one of ordinary skill in

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the art at the time the invention was made to modify the method as taught by Bacon with the ability to treat traumatic brain injury that is a result of a fall on a hard surface, a vehicular accident, or a strike on the head, since it is known in the art that cerebral ischemia can be caused by a fall on a hard surface, a vehicular accident, or a strike on the head.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/27/2007

GEORGE R. EVANISKO
PRIMARY EXAMINER
8/27/7